

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
SteriLance Medical(Suzhou)Inc.	No.168 PuTuoShan Road,New District,215153 Suzhou,Jiangsu, PEOPLE'S REPUBLIC OF CHINA	CN-MF-000002860

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
Emergo Europe B.V.	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	Type	EMDN Code
Disposable Surgical Blades	Stitch cutter(carbon steel)	V010302
	Stitch cutter(stainless steel)	
Intended Purpose		Basic UDI-DI
The blade is mounted on the scalpel handle and used to cut soft tissues.		Stitch cutter(carbon steel) : 6945630114BJ Stitch cutter(stainless steel):6945630115BL

RISK CLASS FOR MEDICAL DEVICES		
Device Classification		Common Specifications / Standards
Class:	Ila	Medical Devices Regulation (EU) 2017/745
Rule:	6	

NOTIFIED BODY			
Name of Company	ID Number	Conformity Assessment Procedure	Certificate Reference(s)
TÜV SÜD Product Service GmbH	 0123	Medical Devices Regulation (EU) 2017/745 ,Annex IX Chapters I and III	Certificate No.: G10 093119 0001 Rev.01 Valid from: 2023-06-19 Valid until: 2027-11-23

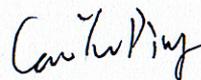
The SteriLance Medical(Suzhou)Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Cao Yueping

TITLE: PRRC

SIGNATURE:



PLACE: Suzhou

DATE:

